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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,512	05/23/2006	Yoshitaka Ichikawa	8031-013-US	2374

32301 7590 03/15/2010

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EXAMINER	
WHITE, EVERETT NMN	

ART UNIT	PAPER NUMBER
1623	

MAIL DATE	DELIVERY MODE
03/15/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/580,512	ICHIKAWA ET AL.	
	Examiner	Art Unit	
	EVERETT WHITE	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 October 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7 and 9-92* is/are pending in the application.

4a) Of the above claim(s) *3-6,12-21 and 47-92* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,7,9-11 and 22-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/23/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed October 28, 2009 has been received, entered and carefully considered. The amendment affects the instant application accordingly:

(A) Claim 8 has been canceled;
(B) Claims 1, 9, 10 and 43-46 have been amended;
(C) Comments regarding Office Action have been provided drawn to:
  (I) 102(b) rejection, rendered moot by new ground of rejection over art already of record;
  (II) 103(a) rejection, rendered moot by new ground of rejection over art already of record.

2. Claims 1-7 and 9-92 are pending in the case. Claims 3-6, 12-21 and 47-92 are withdrawn from consideration as being directed to non-elected inventions.

Information Disclosure Statement

3. The information disclosure statement filed July 23, 2007 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered. See the Bohne, W. Med. Welt. Nr. reference.

4. The information disclosure statement filed July 23, 2007 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. See the Dieppe, P. reference. These references are not legible. A copy of the Fingl, E. et al was not provided.

Claim Rejections - 35 USC § 112

New Ground of Rejection

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 9 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claim 9, line 7, it is not clear what the compound "aminitol" is or what structure the compound represents, which renders the claim indefinite.

The dependence of Claim 11 from Claims 10 and 1 renders Claim 11 indefinite for lack of clarity because Claim 1, last 2 lines, recites "wherein the derivative of glucosamine is not N-acetyl glucosamine," but the formula of Claim 11 as currently written still comprises N-acetyl glucosamine when R_1 is hydroxyl, R_2 is acetyl and when R_3 is hydroxyl.

7. Applicant's arguments with respect to Claims 9 and 10 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

New Ground of Rejection

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

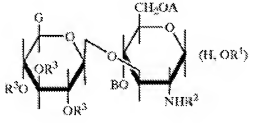
> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 2, 10, 11, 22, 31, 32, 39-41 and 43-46 are rejected under 35 U.S.C. 102(b) as being anticipated by Villa Pahi et al (WO 02/08239 A1, also see English Language equivalent, US Pat. 6,680,304).

Applicants claim a method of treating an osteoarthritis related disorder in a mammal comprising administering a compound to said mammal, wherein said compound further comprises a therapeutically effective amount of an aminosugar

derivative, wherein said aminosugar derivative is a derivative of glucosamine or pharmaceutically acceptable salts thereof, and wherein the derivative of glucosamine is not N-acetyl glucosamine.

The Villa Pahi et al WO publication discloses a disaccharide which can be used as an anti-arthritic agent and anti-inflammatory agent wherein the disaccharide has the formula (I):



(I)

wherein R^1 may be selected as hydrogen, a C^1-C^4 alkyl, or $-COCH_3$; R^2 may be selected as hydrogen or $-COCH_3$; and A and B each may be selected as hydrogen (see abstract). Each of R^1 , R^2 , A and B in the above formula of the Villa Pahi et al WO publication anticipates the groups in the same position of the glucosamine derivative of the instant claims. The R^3 position of the glucosamine derivative of the instant claims is represented as a saccharide unit in formula (I) of the Villa Pahi et al publication, but still anticipates the glucosamine derivative of the instant claims since the disaccharide of formula (I) in the Villa Pahi et al publication falls within the scope of the broad instantly claimed derivative of glucosamine and is not N-acetyl glucosamine. The above description of the disaccharide in the Villa Pahi et al WO publication anticipates the derivative of glucosamine recited in instant Claims 1, 10 and 11. See column 9, last paragraph of US Pat. No. 6,680,304 ('304), the English language equivalent of the WO publication, wherein it is disclosed that the compounds thereof has application for the prevention or treatment of osteoarthritis, inflammatory diseases, and rheumatoid arthritis, which anticipate the subject matter of instant Claim 2, 22, 41 and 43-46. The '304 patent also discloses the compounds thereof in pharmaceutical compositions being administered to patients via intra-articular, intramuscular, and topical administrations

(see column 10, lines 17 and 18), which anticipate the subject matter of instant Claims 31, 32, 39 and 40.

10. Applicant's arguments with respect to Claims 1, 2, 10, 11, 22, 31, 32, 39-41 and 43-46 have been considered but are moot in view of the new ground(s) of rejection.

11. Claim 11 stands rejected under 35 U.S.C. 102(b) as being anticipated by Lotz et al (WO 02/078445 A1, already of record) for the reasons disclosed below.

Applicants claim a method of treating an osteoarthritis related disorder in a mammal comprising administering a compound to said mammal, wherein said compound further comprises a therapeutically effective amount of an aminosugar derivative, wherein said aminosugar derivative is a derivative of glucosamine or a pharmaceutically acceptable salts thereof, and wherein the formula recited in instant Claim 11 covers N-acetyl glucosamine when R_1 is hydroxyl, R_2 is acetyl and when R_3 is hydroxyl.

The Lotz et al publication discloses a method of treating cartilage degradation in a patient that involve administering to a patient a composition containing a therapeutically effective amount of an aminosugar which may be selected as N-acetyl glucosamine (see page 31, lines 7 and 10), wherein the N-acetyl glucosamine anticipate the formula of the glucosamine derivative recited in instant Claim 11.

12. Applicant's arguments filed October 28, 2009 have been fully considered but they are not persuasive. The formula recited in instant Claim 11 still comprises N-acetyl glucosamine.

Claim Rejections - 35 USC § 103

New Ground of Rejection

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

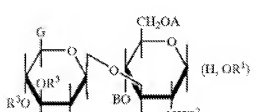
The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. Claims 1, 2, 7, 10, 11 and 22-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Villa Pahi et al (WO 02/08239 A1, also see English Language equivalent, US Pat. 6,680,304).

Applicants claim a method of treating an osteoarthritis related disorder in a mammal comprising administering a compound to said mammal, wherein said compound further comprises a therapeutically effective amount of an aminosugar derivative, wherein said aminosugar derivative is a derivative of glucosamine or pharmaceutically acceptable salts thereof, and wherein the derivative of glucosamine is not N-acetyl glucosamine.

The Villa Pahi et al WO publication discloses a disaccharide which can be used as an anti-arthritic agent and anti-inflammatory agent wherein the disaccharide has the formula (I):



(I)

wherein R^1 may be selected as hydrogen, a C^1-C^4 alkyl, or $-COCH_3$; R^2 may be selected as hydrogen or $-COCH_3$; and A and B each may be selected as hydrogen (see abstract); Each of R^1 , R^2 , A and B in the above formula of the Villa Pahi et al WO publication anticipates the groups in the same position of the glucosamine derivative of the instant claims. The R^3 position of the glucosamine derivative of the instant claims is represented as a saccharide unit in formula (I) of the Villa Pahi et al publication, but still embraces the glucosamine derivative of the instant claims since the disaccharide of formula (I) in the Villa Pahi et al publication falls within the scope of the broad instantly claimed derivative of glucosamine and is not N-acetyl glucosamine. The above description of the disaccharide in the Villa Pahi et al WO publication embraces the derivative of glucosamine recited in instant Claims 1, 10 and 11. See column 9, last paragraph of US Pat. No. 6,680,304 ('304), the English language equivalent of the WO publication, wherein it is disclosed that the compounds thereof has application for the prevention of treatment of osteoarthritis, inflammatory diseases, and rheumatoid arthritis, which embrace the subject matter of instant Claim 2, 22, 41 and 43-46. The '304 patent also discloses the compounds thereof in pharmaceutical compositions being administered to patients via intra-articular, intramuscular, and topical administrations (see column 10, lines 17 and 18), which embrace the subject matter of instant Claims 31, 32, 39 and 40. The '304 patent also disclose pharmaceutical preparations in solid form being converted, immediately before use, into preparations in liquid forms, for intra-articular administration, wherein the liquid form include solution, suspensions and emulsions (see column 10, lines 36 to 40), which embraces the intra-articular administration as a controlled release formula as recited in instant Claims 33 and 34. The instantly claimed properties recited in instant Claims 23-30 are inherent properties of the

aminosugar derivative of the Villa Pahi et al publication since products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada* 15 USPQ 2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01

The instantly claimed method of treating osteoarthritis related disorder in a mammal differs from the anti-arthritic treatment of the Villa Pahi et al WO publication by reciting in the claims that the osteoarthritis related disorder is cartilage degradation.

However, the Villa Pahi et al publication does disclose the disaccharide thereof being administered to patients to treat osteoarthritis. Since osteoarthritis is a type of arthritis that is caused by the breakdown and eventual loss of cartilage of one or more joints, it appears that treatment of osteoarthritis would include treatment of cartilage degradation as instantly claimed.

One having ordinary skill in the art would have been motivated to employ the method of the prior art with the expectation of obtaining the desired result because the skilled artisan would have expected the analogous starting materials to react similarly.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of Applicants invention to replace the treatment of osteoarthritis in the Villa Pahi et al WO publication with a treatment of cartilage degradation in view of the closely related relationship of the disorders with regard to loss of cartilage.

15. Applicant's arguments with respect to Claims 1, 2, 7, 10, 11 and 22-46 have been considered but are moot in view of the new ground(s) of rejection.

Summary

16. Claims 1, 2, 7, 9-11 and 22-46 are rejected; Claims 3-6, 12-21 and 47-92 are withdrawn from consideration.

Conclusion

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Examiner's Telephone Number, Fax Number, and Other Information

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is 571-272-0660. The examiner can normally be reached on 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Everett White/
Examiner, Art Unit 1623

/Shaojia Anna Jiang/
Supervisory Patent Examiner, Art Unit 1623